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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,763	09/17/2001	Paul J. Thompson	11576.51USI1	8878
23552	7590	07/14/2004	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			WEBB, SARAH K	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/954,763	Applicant(s) THOMPSON ET AL.	
	Examiner Sarah K Webb	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 9, 12, 16, 22 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 11, 13, 14, 17-21, 23 and 25-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/10/03</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

1. Claim 9 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claim 9 does not read on the elected species of Figure 15.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-8,10,11,13,14,19-21,23,25-29,34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 10,11,16,18,24, and 25 of U.S. Patent No. 6,623,491 to Thompson.

Although the conflicting claims are not identical, they are not patentably distinct from each other because some of the independent limitations in the '491 patent were simply put into dependent form in the application.

Claim Objections

3. Claim 13 is objected to because of the following informalities: the wording in lines 1 and 2 should be changed to "said splines *are coupled* to said inner tubular member." Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 25,26, 28,29,31 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,129,700 to Fitz.

As clearly illustrated in Figure 5, the device includes an outer tubular member (22), inner tubular member (16), fluid channel (24) between the outer and inner tubular members, and stent (14) mounted on the distal end of the inner tubular member (16). It is inherent from the disclosure that a port in communication with the fluid channel (24) is included to provide fluid to the channel (24).

A discharge opening (54), or "fluid exchange aperture", at the distal end of the outer tubular member (22) allows fluid to flow from the fluid channel (24) to a patient's lumen (column 4, lines 25-35). There is a plurality of such apertures (54), and the apertures (54) are located on the portion of the outer tubular member (22) covering the stent. The stent is self-expanding (column 3, line 41) and is deployed by retracting the

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outer tubular member (22) (column 4, line 64), as shown in Figure 7. The inner tubular member (16) is hollow and defines a guide wire lumen (18).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-8,10,11,13,14,17-21,23,33, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fitz in view of US Patent No. 5,279,546 to Mische et al.

As explained above, Fitz discloses a stent delivery catheter that includes most of the limitations of claim 1. Fitz fails to include a plurality of spacers in the fluid channel. Mische discloses a similar balloon catheter device. Mische includes an outer tubular member (70) and an inner tubular member (72) that define a fluid channel in between them. A plurality of spaced apart spacer members (134,136,138,140) are positioned in the lumen between the two tubular members (see Figure 3). Mische teaches that the spacers (134,136,138,140) provide resistance to luminal collapse (column 5, lines 35-36). The spacers also extend a majority of the longitudinal length of the catheter system, as this structure extends from the proximal hub (10) to the distal balloon section (74). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include spacers along the majority of the length of the lumen between the inner and outer tubular members of Fitz, as Mische teaches that this structure provides the catheter with resistance to luminal collapse.

The spacers are considered to meet the limitation of "splines." Further, the splines of Mische are coupled to the inner tubular member (72) and project outwardly toward the outer member (70).

Regarding claims 17 and 18, a surface capable of being thermally bonded falls within the scope of "a thermal bonding surface." Mische clearly includes a surface on the spacers that is capable of receiving a thermal bonding treatment to fixedly couple the inner and outer tubular members.

6. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fitz in view of US Patent No. 5,005,584 to Little.

Fitz includes all the limitations of claim 30, except for a pressure measuring device. Little discloses a guide wire that measures fluid pressure and is capable of being used with the Fitz device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the Little guide wire for the guide wire of Fitz, as this produces a combination that is capable of measuring fluid pressure within a passageway.

7. Claims 27 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fitz in view of US Patent No. 5,571,086 to Kaplan et al.

Fitz includes all the limitations of claims 27 and 32 except for providing fluid exchange apertures at both the proximal and distal ends of the stent. Kaplan discloses an outer catheter that can be used with a stent delivery catheter (abstract, line 7). Figure 13D best illustrates an array of fluid exchange apertures (218) positioned along the catheter (200). Kaplan teaches by illustration that the array of apertures (218) can

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extend over a length of a catheter (200) to encompass both the proximal and distal ends of a dilation balloon. The balloon (280) here would be analogous to the stent location area of Fitz. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include apertures in the outer tubular member at both the proximal and distal ends of the stent area of Fitz, as Kaplan teaches that this is another way to convey fluids to a patient's lumen from a catheter.

Response to Arguments

8. Applicant's arguments with respect to claims 1-8,10,11,13,14,17-21, and 25-34 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (703) 605-1176. The examiner can normally be reached on Mon-Fri 8-4:30.

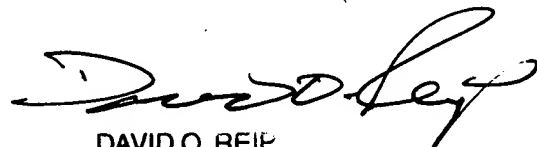
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott or Shaver can be reached on (703) 308-0858. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW
07/09/2004

SKW



DAVID O. REIP
PRIMARY EXAMINER